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HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

M2631n

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER

NWE-24-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 19, 1999

John Campanale
President
Merrimac Smoked Fish, Inc.
955 South Main Street
Great Barrington, MA 01230

Dear Mr. Campanale:

On March 2 and 3,1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 955 South Main Street, Great Barrington, MA 01230. The investigators documented violations of Section 402 (a)(4) of the Federal Food Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21 CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

1. Failure to properly establish the critical limits for the control of the food safety hazard associated with the formation of toxin by *C. botulinum* for at least as long as the shelflife of the product under normal and moderate abuse conditions, as required under 21 CFR 123.16.

   Documentation must be provided that the critical limits set at the critical control points of brining, smoking, and/or drying steps consistently results in a critical limit of 3.5% water phase salt or more in the finished product in vacuum packages. Water phase salt measurements should be taken until it is documented that the critical limit is consistently achieved under the

range of processing conditions in your process (e.g., species of fish, thickness of fish).

Documentation must be provided that the various heat treatments used at the cook/smoke/dry steps results in a minimum of 145 F for 30 min.

However, if the product is frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before us, then formation of *C. botulinum* toxin may not be a significant hazard during storage and distribution.

2. Failure to identify a critical control point as required under 21 CFR 123.(c)(2), e.g., brining should be listed as a critical control point, product storage temperature should be monitored.

3. Failure to provide an adequate recordkeeping system as required under 123.6(c)(7), e.g., your firm does not routinely maintain records of the brining step, cooking/smoking/drying step or finished product storage.

4. Failure to implement appropriate monitoring procedures as required under 123.6(c)(4), e.g., your plan does not specify who will perform the monitoring nor how often.

5. Sanitation monitoring is inadequate, 21 CFR 123.11(b). Your firm does not maintain any sanitation monitoring records. Sanitation observations were also noted during the inspection.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these and all violations at your firm. Failure to achieve corrective action may result in further regulatory action without further notice. These actions may include seizure or injunction under the Federal Food, Drug, and Cosmetic Act. In addition, failure to correct the above deficiencies may affect your firm's ability to obtain European Union certificates. As you know, FDA, as a service to the US seafood industry to facilitate the free flow of trade, has voluntarily undertaken to certify that seafood exports meet the EU's food safety requirements. Unless the above deficiencies are corrected, FDA may remove your firm from the EU list. In addition, until these deficiencies are corrected, the agency may not issue EU certificates for shipments.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 279-1675, Extension 113.

Sincerely,

John Marzilli
District Director
New England District Office